

09/613, 508.

Cofe

Docket No.: PF140P1D1  
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Letters Patent of:  
He et al.

Patent No.: 6,835,555 B1

Issued: December 28, 2004

For: Interleukin-1  $\beta$  Converting Enzyme Like  
Apoptosis Protease-3 and 4

Certificate  
MAR 03 2005  
of Correction

**REQUEST FOR CERTIFICATE OF  
CORRECTION PURSUANT TO 37 CFR 1.322**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Upon reviewing the above-identified patent, Patentee noted typographical errors, as well as errors of omission, which should be corrected.

**On the Cover Page:**

Under "References Cited," insert the following references, which were filed by Applicants and initialed by the Examiner:

-- OTHER PUBLICATIONS

Kamens, et al., "Identification and Characterization of ICH-2, a Novel Member of the Interleukin-1 $\beta$ -converting Enzyme Family of Cysteine Proteases," *J. Biol. Chem.*, 270(25):15250-15256 (1995). The American Society for Biochemistry and Molecular Biology, Inc., U.S.A.

Munday, et al., "Molecular Cloning and Pro-apoptotic Activity of ICE<sub>rel</sub>II and ICE<sub>rel</sub>III, Members of the ICE/CED-3 Family of Cysteine Proteases," *J. Biol. Chem.*, 270(26):15870-15876 (1995). The American Society of Biochemistry and Molecular Biology, Inc., U.S.A.

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Tewari, et al., "Yama/CPP32 $\beta$ , a Mammalian Homolog of CED-3, Is a Crm-A-Inhibitable Protease That Cleaves the Death Substrate Poly (ADP-Ribose) Polymerase," *Cell*, 81:801-809 (1995). Cell Press.

Faucheu, et al., "A Novel Human Protease Similar to the Interleukin-1 $\beta$  Converting Enzyme Induces Apoptosis in Transfected Cells," *The EMBO Journal*, 14(9):1914-1922 (1995).

Greenfeder, et al., "Molecular Cloning and Characterization of a Second Subunit of the Interleukin 1 Receptor Complex," *J. Biol. Chem.*, 270(23):13757-13765 (June 9, 1995). The American Society for Biochemistry and Molecular Biology, Inc., U.S.A.

Miura, et al., "Induction of Apoptosis in Fibroblases by IL-1 $\beta$ -Converting Enzyme, a Mammalian Homolog of the *C. elegans* Cell Death Gene *ced-3*," *Cell*, 75:653-660 (November 19, 1993). Cell Press.

Fernandes-Alnemri, et al., "CPP32, a Novel Human Apoptotic Protein with Homology to *Caenorhabditis elegans* Cell Death Protein Ced-3 and Mammalian Interleukin-1 $\beta$ -converting Enzyme," *J. Biol. Chem.*, 269(49):30761-30764 (December 9, 1994). The American Society for Biochemistry and Molecular Biology, Inc., U.S.A.

Ellis, et al. "Mechanisms and Functions of Cell Death," *Annu. Rev. Cell Biol.*, 7:663-698 (1991). Annual Reviews, Inc.

Barinaga, M., "Cell Suicide: By ICE, Not Fire," *Science*, 263:754-756 (February 11, 1994).

Callard, et al., "The Cytokine Facts Book," New York: Academic Press (1994), p. 31. --

**In the Specification:**

At column 2, line 60, delete "CDNA" and replace with "cDNA sequence (SEQ ID NO:1)"; and

At column 2, line 66, delete "CDNA" and replace with "cDNA".

In support of the above request, Patentees respectfully note that the references to be cited on the cover page of the issued patent were cited on the Information Disclosure Statement form PTO-1449, submitted November 1, 2001, in connection with the present application. The Examiner-initialed copy of the Information Disclosure Statement is attached hereto as Exhibit A.

Furthermore, Patentees point out that the specification was amended as shown above in the Preliminary Amendment submitted July 10, 2000 in connection with the present application, a copy of which is attached hereto as Exhibit B.

The above mistakes were not in the application as filed or amended by Patentees, and thus appear to be the fault of the Patent and Trademark Office. Accordingly, it is hereby requested that a Certificate of Correction under 37 C.F.R. § 1.322 be issued for the above-identified patent. Pursuant to 35 U.S.C. § 254 and 37 C.F.R. § 1.322, no fee is required.

Submitted herewith is a proposed Certificate of Correction (Form PTO/SB/44). Patentees respectfully request the issuance of the Certificate of Correction.

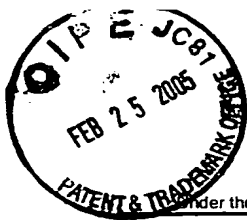
Dated: February 25, 2005

Respectfully submitted,

By MJH  
Mark J. Hyman

Registration No.: 46,789  
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KKH/MJH/ZS/mr



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<b>Effective on 12/08/2004.</b> <b>Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).</b> <b>FEE TRANSMITTAL</b> <b>For FY 2005</b>		<b>Complete if Known</b>	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		Application Number	Patent#: 6,835,555
<b>TOTAL AMOUNT OF PAYMENT</b> (\$ ) 0.00		Filing Date	Issued: December 28, 2004
		First Named Inventor	Wei-Wu He
		Examiner Name	G. E. Bugaisky
		Art Unit	1653
		Attorney Docket No.	PF140P1D1

**METHOD OF PAYMENT** (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_

☒ Deposit Account      Deposit Account Number: 08-3425      Deposit Account Name: Human Genome Sciences, Inc.

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below      ☐ Charge fee(s) indicated below, except for the filing fee

☒ Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17      ☒ Credit any overpayments

**FEE CALCULATION**

**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES**

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

**Total Claims**      **Extra Claims**      **Fee (\$)**      **Fee Paid (\$)**

\_\_\_\_\_ - 20 = \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_

**Indep. Claims**      **Extra Claims**      **Fee (\$)**      **Fee Paid (\$)**

\_\_\_\_\_ - 3 = \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
_____ - 100 = _____	/50	_____ (round up to a whole number) x _____	= _____	

**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): \_\_\_\_\_

**Fees Paid (\$)**

<b>SUBMITTED BY</b>			
Signature		Registration No. (Attorney/Agent)	46,789
Name (Print/Type)	Mark J. Hyman	Telephone	(240) 314-1224
		Date	2/25/2005

## UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

PATENT NO. : 6,835,555 B1  
DATED : December 28, 2004  
INVENTOR(S) : He, et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected  
as shown below:

**On the Cover Page:**

Under "References Cited," insert the following references:

-- OTHER PUBLICATIONS

Kamens, et al., "Identification and Characterization of ICH-2, a Novel Member of the Interleukin-1 $\beta$ -converting Enzyme Family of Cysteine Proteases," *J. Biol. Chem.*, 270(25):15250-15256 (1995). The American Society for Biochemistry and Molecular Biology, Inc., U.S.A.

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Ellis, et al. "Mechanisms and Functions of Cell Death," *Annu. Rev. Cell Biol.*, 7:663-698 (1991). Annual Reviews, Inc.

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No. of additional copies: 1

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PATENT NO.: 6,835,555 B1

No. of additional copies: 1

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Approved for: PTO/SB/08A (10-96)  
Patent and Trademark Office: U.S. Department of Commerce  
Effective Date: 10/31/99. OMB 0651-0031

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Substitute for form 1449A/PTO				Complete If Known				
INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (use as many sheets as necessary)								
Application Number		09/613,508						
Filing Date		July 10, 2000						
First Named Inventor		He et al.						
Group Art Unit		1653						
Examiner Name		Bugaisky, G.						
Attorney Docket Number		PF140P1D1						
Sheet	1	of	4					
U.S. PATENT DOCUMENTS								
Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document Number	Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
	AA	09/913,293		ROSEN et al.	NOT PUBLISHED	pages 1-75 (pages 1 & 2 partially redacted); portion of Table 2; and SEQ ID NOS: 103167, 179522, 187075, and 202317		
	AB	09/913,292		ROSEN et al.	NOT PUBLISHED	pages 1-75 (pages 1 & 2 partially redacted); portion of Table 2; and SEQ ID NO: 14507		
	AC	5,552, 536		NICHOLSON et al.	09-03-96			
FOREIGN PATENT DOCUMENTS								
Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	AD		WO96/33268		MERCK & CO., INC. et al.	10-24-96		
	AE		EP 0 533 226		MERCK & CO., INC.	03-24-93		
	AF		CA 2075662		MERCK & CO., INC.	02-17-93		
OTHER REFERENCES - NON PATENT LITERATURE DOCUMENTS								
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.						T <sup>6</sup>
	AG	GeneSeq Accession No. T66992 (08-05-97) IDUN PHARM., INC. et al., "Apototic protease Mch3-alpha cDNA"						
	AH	GeneSeq Accession No. T66970 (07-21-97) VERTEX PHARM., INC., "Cysteine protease CMH-1 cDNA"						
	AI	GeneSeq Accession No. T66993 (08-05-97) IDUN PHARM., INC., "Cysteine protease Mch3-beta cDNA"						
	AJ	GeneSeq Accession No. W15247 (07-21-97) VERTEX PHARM., INC., "Cysteine protease CMH-1"						
	AK	GeneSeq Accession No. W15262 (08-05-97) IDUN PHARM., INC., "Apototic protease Mch3-alpha"						
	AL	GeneSeq Accession No. W15263 (08-05-97) IDUN PHARM., INC., "Cysteine protease Mch3-beta"						
	AM	GenBank Accession No. U39613 (01-19-96) DUAN et al., "Human cysteine protease ICE-LAP3 mRNA"						
	AN	GenBank Accession No. U37448 (12-14-95) PERNANDES-ALNEMRI et al., "Human Mch3 isoform alpha (Mch3) mRNA"						
	AO	GenBank Accession No. U40281 (01-27-96) LIPPKE et al., "Human cysteine protease CMH-1 mRNA"						
Examiner				Date Considered				
8/12/2002				8/12/2002				

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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIP Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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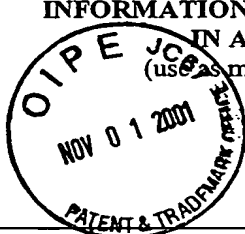
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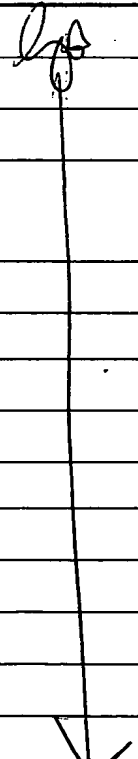
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<b>INFORMATION DISCLOSURE STATEMENT</b> <b>IN AN APPLICATION</b> (use as many sheets as necessary)			
		Application Number	09/613,502
		Filing Date	July 10, 2000
		First Named Inventor	He et al.
		Group Art Unit	1653
		Examiner Name	Bugaisky, G.
Sheet 2 of 4	Attorney Docket Number	PF140P1D1	

U.S. PATENT DOCUMENTS						
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FOREIGN PATENT DOCUMENTS								
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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				

OTHER REFERENCES - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	AP	GenBank Accession No. U67319 (03-19-97) JUAN et al., "Human Lice2 beta cysteine protease mRNA"	
	AQ	GenBank Accession No. U67320 (03-19-97) JUAN et al., "Human Lice2 gamma cysteine protease mRNA"	
	AR	GenBank Accession No. U37449 (12-14-95) FERNANDES-ALNEMRI et al., "Human Mch3 isoform beta (Mch3) mRNA"	
	AS	GenBank Accession No. H91868 (11-29-95) HILLIER et al., "ys81a06.rl Soares retina N2b4HR Homo sapiens cDNA clone IMAGE:221170 5' similar to SP:A49429 A49429 CED-3+INTERLEUKIN-1 BETA-CONVERTING ENZYME HOMOLOG - CAENORHABDITIS ;, mRNA sequence"	
	AT	GeneSeq Accession No. V05471 (07-02-98) UNIV. MICHIGAN, "Nucleic acid encoding a protein designated YAMA"	
	AU	GeneSeq Accession No. T33567 (12-06-96) UNIV. MICHIGAN, "Pro-Yama cDNA"	
	AV	GeneSeq Accession No. V32608 (10-26-98) MERCK FROSST CANADA, INC., "Mutant human apopain (caspase-3) pro-enzyme cDNA"	
	AW	GeneSeq Accession No. V32615 (10-26-98) MERCK FROSST CANADA, INC., "Mutant human apopain (caspase-3) pro-enzyme cDNA"	
	AX	GeneSeq Accession No. W00677 (12-06-96) UNIV. MICHIGAN, "Pro-Yama"	
	AY	GeneSeq Accession No. W00372 (06-26-97) MERCK & CO., INC. et al., "Apopain CPP32beta proenzyme"	
	AZ	GeneSeq Accession No. W41688 (07-02-98) UNIV. MICHIGAN, "Amino acid sequence of a protein designated YAMA"	
	BA	GeneSeq Accession No. W16600 (06-26-97) MERCK & CO., INC. et al., "Apopain CPP32a proenzyme"	
	BB	GeneSeq Accession No. W48945 (10-26-98) MERCK FROSST CANADA, INC., "Mutant human apopain (caspase-3) C163S pro-enzyme"	
	BC	GeneSeq Accession No. W48937 (10-26-98) MERCK FROSST CANADA, INC., "Mutant human apopain (caspase-3) C163S pro-enzyme"	

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIP Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Approved for use through 10/31/99. OMB 0651-0031  
Patent and Trademark : U.S. Department of Commerce

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Substitute for form 1449A/PTO				Complete If Known			
<b>INFORMATION DISCLOSURE STATEMENT</b> <b>IN AN APPLICATION</b> (use as many sheets as necessary)				Application Number		09/613,508	
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				First Named Inventor		He et al.	
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				Attorney Docket Number		PF140P1D1	
Sheet	3	of	4				
<b>U.S. PATENT DOCUMENTS</b>							
Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document Number	Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
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<b>OTHER REFERENCES - NON PATENT LITERATURE DOCUMENTS</b>							
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	BD	GenBank Accession No. U26943 (08-29-95) TEWARI et al., "Human cysteine protease Yama mRNA"					
	BE	GenBank Accession No. U13737 (04-14-95) FERNANDES-ALNEMRI et al., "Human cysteine protease CPP32 isoform alpha mRNA"					
	BF	GenBank Accession No. U13738 (04-14-95) FERNANDES-ALNEMRI et al., "Human cysteine protease CPP32 isoform beta mRNA"					
	BG	GenBank Accession No. T10341 (06-07-94) SOARES et al., "seq1254 b4HB3MA Cot8-HAP-Ft Homo sapiens cDNA clone b4HB3MA-COT8-HAP-Ft280 5' similar to similar to Human Cysteine proteinase and to Mouse interleukin 1-beta convertase, mRNA sequence"					
	BH	GenBank Accession No. H29199 (07-17-95) HILLIER et al., "ym31f1.1.rl Soares infant brain 1NIB Homo sapiens cDNA clone IMAGE:49729 5' similar to SP:A49429 A49429 CED-3=INTERLEUKIN-1 BETA-CONVERTING ENZYME HOMOLOG - CAENORHABDITIS ;, mRNA sequence"					
	BI	GenBank Accession No. N85243 (04-01-96) LIEW, C.C., "J2957F Human fetal heart, Lambda ZAP Express Homo sapiens cDNA clone J2957 5' similar to CYSTEINE PROTEASE CPP32, mRNA sequence"					
	BJ	CERRETTI et al., "Molecular Cloning of the Interleukin-1 $\beta$ Converting Enzyme," <i>Science</i> , 256:97-100 (04-03-92).					
	BK	WALKER et al., "Crystal Structure of the Cysteine Protease Interleukin-1 $\beta$ -Converting Enzyme: A (p20/p10) <sub>2</sub> Homodimer," <i>Cell</i> , 78:343-352 (07-29-94), Cell Press.					
	BL	WANG et al., "Ich-1, an Ice/ced-3-Related Gene, Encodes Both Positive and Negative Regulators of Programmed Cell Death," <i>Cell</i> , 78:739-750 (09-09-94), Cell Press.					
	BM	HENKART, P., "ICE Family Proteases: Mediators of All Apoptotic Cell Death?," <i>Immunity</i> , 4:195-201 (03-96), Cell Press.					
Examiner	Date Considered						
	8/12/2001						

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIP Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449A/PTO		Complete If Known	
<b>INFORMATION DISCLOSURE STATEMENT</b> <b>IN AN APPLICATION</b> (Use as many sheets as necessary)		Application Number	09/613,508
		Filing Date	July 10, 2000
		First Named Inventor	He et al.
		Group Art Unit	1653
		Examiner Name	Bugaisky, G.
		Attorney Docket Number	PF140PID1
Sheet	4	of	4

**U.S. PATENT DOCUMENTS**

FOREIGN PATENT DOCUMENTS							
Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document Office <sup>3</sup> Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>

OTHER REFERENCES - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
GA   <			

Examiner 	Date Considered 8/12/2000
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Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIP Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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MAR 4 2005

HUMAN GENOME SCIENCES, INC.

Applicants: He, et al.

Docket No. PF140P1D1

Application No.: Not yet assigned

Filed: Concurrently herewith

Title: Interleukin-1  $\beta$  Converting Enzyme Like Apoptosis Protease-3 and 4

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Documents Filed Via Hand Delivery on July 10, 2000

1. Postcards (2);
2. Utility Patent Application Transmittal Sheet (in duplicate);
3. Fee Transmittal Sheet (in duplicate);
4. Preliminary Amendment With Statement Under 37 CFR §1.821(e) and (f) and Substitute Sequence Listing (8 pages);
5. Power of Attorney By Assignee of Entire Interest-Revocation of Prior Power of Attorney;
6. Copy of the Declaration as filed in Serial No. 08/462,969 (parent case);
7. 54 pages of specifications, including 10 pages of the sequence listing, 4 pages of claims, 1 page of abstract and 3 sheets of informal drawings (Figs. 1-3)
8. Submission of Formal Drawings including 7 sheets of formal drawings (Figs. 1A-B, 2A-B, 3A-C)
9. Declaration Under 37 CFR §1.132 w/Exhibits A-E

KKH/ba

Attn.: Legal Dept.

HUMAN GENOME SCIENCES, INC.

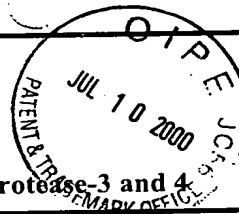
Applicants: He, et al.

Docket No. PF140P1D1

Application No.: Not yet assigned

Filed: Concurrently herewith

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KKH/ba

Attn.: Legal Dept.

MAR 4 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: He, et al.

Application Serial No.: Not yet assigned      Art Unit: Not yet assigned  
Filed: Concurrently herewith      Examiner: Not yet assigned  
For: Interleukin-1  $\beta$  Converting Enzyme      Attorney Docket No.: PF140P1D1  
Like Apoptosis Protease-3 and 4

**PRELIMINARY AMENDMENT**  
**WITH STATEMENT UNDER 37 C.F.R. §§ 1.821(e) and (f)**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Prior to examination, Applicants hereby request that the following amendments and remarks be entered into the subject application.

**In the Specification:**

On page 1, underneath the Title "INTERLEUKIN-1  $\beta$  CONVERTING ENZYME LIKE APOPTOSIS PROTEASE-3 AND 4", please insert the following:

**--CROSS-REFERENCES TO RELATED APPLICATIONS**

This application is a divisional of Application No. 08/462,969, filed June 5, 1995, which is a continuation-in-part of Application Serial No. 08/334,251, filed November 1, 1994, each of which is hereby incorporated by reference in its entirety.--

On page 4, line 20, please insert before the paragraph beginning with the phrase "The following drawings . . .", the heading:

**--Brief Description of the Drawings--.**

On page 4, line 23, delete "Figure 1" and replace therewith --Figures 1A-B--, and delete "cDNA" and replace therewith --cDNA sequence (SEQ ID NO:1)--.

On page 4, line 24, delete "sequence" and replace therewith --sequence (SEQ ID NO:2)--.

On page 4, line 28, delete "Figure 2" and replace therewith --Figures 2A-B--, and delete "cDNA" and replace therewith --cDNA sequence (SEQ ID NO:1)--.

On Page 4, line 29, delete "sequence" and replace therewith --sequence (SEQ ID NO:2)--.

On page 4, line 32, delete "Figure 3" and replace therewith --Figures 3A-C--.

On page 5, line 4, delete Figures 1 and 2" and replace therewith --Figures 1A-B and 2A-B--.

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On page 5, line 11, insert before the paragraph beginning with the phrase "The polynucleotide encoding ICE-LAP-3" the following:

--These deposits are biological deposits with the American Type Culture Collection ("ATCC") located at 10801 University Boulevard, Manassas, Virginia 20110-2209. Since the deposits referred to are being maintained under the terms of the Budapest Treaty, they will be made available to a patent office signatory to the Budapest Treaty.--

On page 5, line 20, delete "hoholog" and replace therewith --homolog--.

On page 5, line 24, delete "259-263" and replace therewith --184-188--.

On page 6, line 5, delete "Figures 1 and 2" and replace therewith --Figures 1A-B and 2A-B--.

On page 6, line 10, delete "Figures 1 and 2" and replace therewith --Figures 1A-B and 2A-B--.

On page 6, line 13, delete "Figures 1 and 2" and replace therewith --Figures 1A-B and 2A-B--.

On page 6, line 29, delete "Figures 1 and 2" and replace therewith --Figures 1A-B and 2A-B--.

On page 6, line 35, delete "Figures 1" and replace therewith --Figures 1A-B--.

On page 7, line 1, delete "2" and replace therewith --2A-B--.

On page 7, line 5, delete "1 and 2" and replace therewith --1A-B and 2A-B--.

On page 7, line 11, delete "Figures 1 and 2" and replace therewith --Figures 1A-B and 2A-B--.

On page 8, line 31, delete "Figures 1" and replace therewith --Figures 1A-B--.

On page 8, line 32, delete "2" and replace therewith --2A-B--.

On page 9, line 29, delete "Figures 1 and 2" and replace therewith --Figures 1A-B and 2A-B--.

On page 10, line 8, delete "Figures 1 and 2" and replace therewith --Figures 1A-B and 2A-B--.

On page 38, line 4, delete "Example 5" and replace therewith --Example 7--.

#### **In the Sequence Listing:**

Please delete the Sequence Listing at pages 40-49 of the specification and replace it with the Substitute Sequence Listing submitted herewith. Additionally, please renumber the claims accordingly.

#### **In the Drawings:**

Please replace the originally filed Figures 1-3 with the Formal Drawings of Figures 1A-B, 2A-B and 3A-C submitted concurrently herewith.

## REMARKS

The specification has been amended to claim benefit of prior filed applications in accordance with 37 C.F.R. § 1.78(a)(2), to conform to current Patent Office practice requiring reference to the lettered subparts of the formal drawings submitted herewith, to correct typographical errors, to update the address of the American Type Culture Collection, to incorporate sequence identifiers pursuant to 37 C.F.R. § 1.821(d), to incorporate the Substitute Sequence Listing submitted herewith pursuant to 37 C.F.R. § 1.821(c) and renumber the pages of the claims accordingly. Additionally, the specification has been amended on page 5 to correct the location of the pentapeptide QACRG in SEQ ID NO:2. No new matter has been added.

A substitute sequence listing and substitute Figures 1A-B and 3A-C are submitted herewith to correct nucleotide and amino acid sequence errors as originally presented in the ICE-LAP 3 sequences (shown in the sequence listing as SEQ ID NOS:1 and 2). These changes do not introduce new matter because the correct sequence was inherent to the originally sequenced plasmid clone in actual possession of the Applicants before the time the captioned application was filed.

The captioned application is directed to both polynucleotides and polypeptides which are chemical compounds. The nucleotide sequence is but an inherent property of the described polynucleotides. There is a line of chemical case law where applicants have been permitted to amend the specification to correct the formula of a chemical compound after an application's filing date, provided that it had been demonstrated that one of skill in the art would have appreciated that the applicant was in possession of the compound itself at the time of filing. The rationale is that the formula is an inherent property of the compound and thus amending the specification to correct the formula is not new matter. See *In re Nathan*, 140 U.S.P.Q. 601, 604 (C.C.P.A. 1964). *Accord Kennecott Corp. v. Kyocera Int'l, Inc.*, 5 U.S.P.Q.2d 1194, 1198 (Fed. Cir. 1987), *cert. denied*, 486 U.S. 1008 (1988) ("The disclosure in a subsequent patent application of an inherent property of a product does not deprive that product of the benefit of the earlier filing date.").

In the field of biotechnology, applicants often rely on a deposited clone, where the deposit was made prior to filing, to establish possession of nucleic acids or proteins. The focus for determining whether applicants were in possession of claimed nucleic acids or proteins has been determined, at least in part, by considering whether the applicant has: (1) established that one skilled in the art in possession of the deposited clone would have been aware of both the DNA sequence and the encoded amino acid sequence, or would be able to determine these sequences without undue experimentation, (2) established that the DNA and amino acid sequences are described in a manner such that one skilled in the art could distinguish them from other sequences, and (3) resequenced a clone which is identical to that of the deposit and established a "chain of custody" for this clone. See

e.g., *Ex parte Maizel*, 27 U.S.P.Q.2d 1662, 1669-1670 (B.P.A.I. 1992).

Submitted herewith is a Declaration of Craig Rosen Under 37 CFR §1.132 (the "Rosen Declaration") which was filed in connection with the prosecution of parent application Serial Number 08/462,969, and which describes certain events involving the characterization of the nucleotide sequence of cDNA clone HE2CA82 which encodes ICE-LAP 3. The HE2CA82 cDNA clone was deposited with the American Type Culture Collection (ATCC) on August 25, 1994; i.e., prior to the filing date of parent application US Serial No. 08/334,251 (filed November 1, 1994). Exhibit A of the Rosen Declaration is a copy of the contract for ATCC Deposit No. 75875. The Examiner will note that the present specification states on page 5, lines 7 and 8, that ATCC Deposit No. 75875 contains the cDNA which encodes ICE-LAP 3.

The corrected nucleic acid and deduced amino acid sequences (shown in replacement Figures 1 and 3 submitted herewith) were determined by reanalyzing cDNA clone HE2CA82 (ATCC Accession No. 75875); i.e., the same cDNA clone from which the originally presented sequences were determined (see paragraph 4 of the Rosen Declaration). The corrected sequence information was published by the present inventors in a peer-reviewed scientific journal article (see Exhibit B of the Rosen Declaration).

The analysis needed to determine the complete and correct sequences of cDNA clone HE2CA82 were well within the skill of the ordinary artisan as of the filing date of the parent application US Serial No. 08/334,251 (filed November 1, 1994), and such analysis would not have required undue experimentation (see paragraph 5 of the Rosen Declaration).

Exhibit D of the Rosen Declaration shows the four (4) nucleotide differences between the original sequence ("PF140" in the Exhibit) and the corrected sequence ("Duan" in the Exhibit).

In summary, because Applicants have demonstrated that the corrected sequences are inherently present in the deposited material, and because Applicants have demonstrated "chain of custody" for the material originally sequenced and the resequenced material, correction of the originally presented sequence information herein is not new matter.

**Statement Under 37 C.F.R. §§ 1.821(e) and (f)**

The above-identified patent application is a divisional of application Serial No. 08/462,969, filed June 5, 1995. The content of the paper copy of the Substitute Sequence Listing filed herewith is identical to the sequence content of the computer readable sequence listing previously filed on March 22, 1999 in connection with application Serial No. 08/462,969.

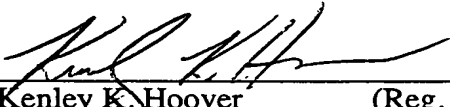
In accordance with 37 C.F.R. § 1.821(e), please use the computer readable form filed on March 22, 1999 in connection with application Serial No. 08/462,969 as the

computer readable form for the instant application. It is understood that the Patent and Trademark Office will make the necessary change in application number and filing date for the computer readable form that will be used for the instant application. A paper copy of the Substitute Sequence Listing is being filed herewith. Applicants hereby certify that the paper copy of the Substitute Sequence Listing filed herewith and the computer readable sequence listing previously filed in connection with application Serial No. 08/462,969 on March 22, 1999 are the same and do not include new matter.

Applicants respectfully request that the amendments and remarks above be entered and made of record in the file history of the instant application.

Respectfully submitted,

Dated: July 10, 2000

  
Kenley K. Hoover (Reg. No. 40,302)  
Attorney for Applicants

**Human Genome Sciences, Inc.**  
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Rockville, MD 20850  
Telephone: (301)

Enclosure